K062569

510(k) Summary of Safety and Effectiveness

Volume 1, Section 5

FEB 14 2007

Date: February 13, 2007

Submitter: Interventional Products Division
Datascope Corp.

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Datascope Corp.
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Device trade name: Safeguard™ 24 cm pressure assisted dressing

Common/usual name: Hemostasis Compression Device

Classification names: 21 CFR 870.4450 Vascular clamp

Predicate Devices: K053300 Syvek$_{excel}$® Vascular Access Hemostasis System
K982182 Femostop®II^{Plus} System

Device Description: The Safeguard 24 cm pressure assisted dressing is a sterile single use pressure bandage which has a medical grade polyurethane window and bladder, a clear medical grade PVC flexible fill tube, and a pressure sensitive, self adhesive peel backing. A luer valve on the end of the fill tube enables a syringe to be connected to inflate the centrally located bladder with air to provide pressure to the puncture site. A check valve allows the fill volume to stay in the bladder after injection from the syringe. The Safeguard 24 cm pressure assisted dressing has a clear window that facilities visualization of the access site without removal or manipulation of the device.

Intended Use: The indications for use for the Safeguard 24 cm pressure assisted dressing are to assist in obtaining and maintaining hemostasis. The device is also indicated in the reduction of active compression time in femoral artery cannulation following diagnostic and interventional procedures, with an ACT of 140 seconds or less, using using a 6 French and smaller sheath size.

Test Summary: Datascope's product development process required that the following activities be completed during the development of the Safeguard pressure assisted dressing:

- Requirements specification review
- Performance bench testing
- Design verification

Clinical testing with the Safeguard 24 cm pressure assisted dressing was conducted in support of the indication for reduction of active compression time in femoral artery compression following diagnostic and interventional procedures.

Conclusion:

The Safeguard 24 cm pressure assisted dressing has essentially the same intended use as the predicate devices. Datascope Corp. has submitted test results regarding biocompatibility, performance and clinical testing to establish that the Safeguard 24 cm pressure assisted dressing is substantially equivalent to the predicate devices. The results of all testing demonstrate that the Safeguard 24 cm pressure assisted dressing is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2007

Datascope
Ms. Denise Daugert
Interventional Products Division
1300 MacArthur Blvd
Mahwah, NJ 07430-0605

Re: K062569
Trade/Device Name: Safeguard™ 24 cm pressure assisted device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: February 14, 2007
Received: February 14, 2007

Dear Ms. Daugert:

This letter corrects our substantially equivalent letter of February 14, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K062569

Device Name: Safeguard™ 24 cm pressure assisted device

Indications For Use:

The indications for use for the Safeguard 24 cm pressure assisted device are to assist in obtaining and maintaining hemostasis. The device is also indicated in the reduction of active compression time in femoral artery cannulation following diagnostic and interventional procedures with an ACT of 140 seconds or less, using a 6 French and smaller sheath size.

Prescription Use ___X____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062569